Appendix B, Table 1. Characteristics of Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

 (Updated January 10, 2011)

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-lives	Adverse Events (Also see Table 13)
Abacavir (ABC)/ Ziagen **Also available as**:	Ziagen - 300-mg tablets - 20-mg/mL oral solution	Ziagen 300 mg BID or 600 mg once daily Take without regard to meals	Metabolized by alcohol dehydrogenase and glucuronyl transferase Renal excretion of metabolites 82% Dosage adjustment for ABC recommended in patients with hepatic insufficiency (See Appendix B, Table 7.)	1.5 hrs/ 12–26 hrs	• *Hypersensitivity reactions (HSR)*: Patients positive for HLA-B*5701 are at highest risk. HLA screening should be done prior to initiation of ABC. Rechallenge is not recommended. • Symptoms of HSR may include fever, rash, nausea, vomiting, diarrhea, abdominal pain, malaise, or fatigue or respiratory symptoms such as sore throat, cough, or shortness of breath. • Some cohort studies suggest increased risk of myocardial infarction (MI) with recent or current use of ABC, but this risk is not substantiated in other studies.
Trizivir ABC with ZDV+3TC	Trizivir ABC 300 mg + ZDV 300 mg + 3TC 150 mg	Trizivir 1 tablet BID			
Epzicom ABC with 3TC	Epzicom ABC 600 mg + 3TC 300 mg	Epzicom 1 tablet once daily			
Didanosine (ddI)/ Videx EC (generic available; dose same as Videx EC)	Videx EC 125-, 200-, 250-, 400-mg capsules Buffered tablets (non-EC) no longer available Videx 10-mg/mL oral solution	**Body weight ≥60kg**: 400 mg once daily* *With TDF*: 250 mg once daily **Body weight <60kg**: 250 mg once daily* *With TDF*: 200 mg once daily Take 1/2 hour before or 2 hours after a meal *Preferred dosing with oral solution is BID (total daily dose divided into 2 doses)	Renal excretion 50% Dosage adjustment in renal insufficiency recommended (See Appendix B, Table 7.)	1.5 hrs/ >20 hrs	• Pancreatitis • Peripheral neuropathy • Retinal changes, optic neuritis • Lactic acidosis with hepatic steatosis +/- pancreatitis (rare but potentially life-threatening toxicity) • Nausea, vomiting • Potential association with noncirrhotic portal hypertension, some cases presented with esophageal varices • One cohort study suggested increased risk of MI with recent or current use of ddI, but this risk is not substantiated in other studies. • Insulin resistance/diabetes mellitus
Emtricitabine (FTC)/ Emtriva **Also available as:**	Emtriva - 200-mg hard gelatin capsule - 10-mg/mL oral solution	Emtriva *Capsule*: 200 mg once daily *Oral solution*: 240 mg (24 mL) once daily Take without regard to meals	Renal excretion 86% Dosage adjustment in renal insufficiency recommended (See Appendix B, Table 7.)	10 hrs/ >20 hrs	• Minimal toxicity • Hyperpigmentation/skin discoloration • Severe acute exacerbation of hepatitis may occur in HBV-coinfected patients who discontinue FTC.
Atripla FTC with EFV+TDF	Atripla FTC 200 mg + EFV 600 mg + TDF 300 mg	Atripla 1 tablet at or before bedtime Take on an empty stomach to reduce side effects			
Truvada FTC with TDF	Truvada FTC 200 mg + TDF 300 mg	Truvada 1 tablet once daily			

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-lives	Adverse Events (Also see Table 13)
Lamivudine (3TC)/ Epivir **Also available as:**	Epivir • 150-, 300-mg tablets • 10-mg/mL oral solution	Epivir 150 mg BID or 300 mg once daily Take without regard to meals	Renal excretion 70% Dosage adjustment in renal insufficiency recommended (See Appendix B, Table 7.)	5–7 hrs/ 18–22 hrs	• Minimal toxicity • Severe acute exacerbation of hepatitis may occur in HBV-coinfected patients who discontinue 3TC.
Combivir 3TC with ZDV	Combivir 3TC 150 mg + ZDV 300 mg	Combivir 1 tablet BID			
Epzicom 3TC with ABC	Epzicom 3TC 300 mg + ABC 600 mg	Epzicom 1 tablet once daily			
Trizivir 3TC with ZDV+ABC	Trizivir 3TC 150 mg + ZDV 300 mg + ABC 300 mg	Trizivir 1 tablet BID			
Stavudine (d4T)/ Zerit	Zerit • 15-, 20-, 30-, 40-mg capsules • 1-mg/mL oral solution	**Body weight ≥60 kg**: 40 mg BID **Body weight <60 kg**: 30 mg BID* Take without regard to meals *WHO recommends 30 mg BID dosing regardless of body weight.	Renal excretion 50% Dosage adjustment in renal insufficiency recommended (See Appendix B, Table 7.)	1 hr/ 7.5 hrs	• Peripheral neuropathy • Lipoatrophy • Pancreatitis • Lactic acidosis/severe hepatomegaly with hepatic steatosis (rare but potentially life-threatening toxicity) • Hyperlipidemia • Insulin resistance/diabetes mellitus • Rapidly progressive ascending neuromuscular weakness (rare)
Tenofovir Disoproxil Fumarate (TDF)/ Viread **Also available as:**	Viread 300-mg tablet	Viread 1 tablet once daily Take without regard to meals	Renal excretion Dosage adjustment in renal insufficiency recommended (See Appendix B, Table 7.)	17 hrs/ >60 hrs	• Renal insufficiency, Fanconi syndrome • Osteomalacia • Potential decrease in bone mineral density • Severe acute exacerbation of hepatitis may occur in HBV-coinfected patients who discontinue TDF. • Asthenia, headache, diarrhea, nausea, vomiting, and flatulence
Atripla TDF with EFV+FTC	Atripla TDF 300 mg + EFV 600 mg + FTC 200 mg	Atripla 1 tablet at or before bedtime Take on an empty stomach to reduce side effects			
Truvada TDF with FTC	Truvada TDF 300 mg + FTC 200 mg	Truvada 1 tablet once daily Take without regard to meals			
Zidovudine (ZDV)/ Retrovir (generic available; dose same as retrovir) **Also available as**:	Retrovir • 100-mg capsules • 300-mg tablets • 10-mg/mL intravenous solution • 10-mg/mL oral solution	Retrovir 300 mg BID or 200 mg TID Take without regard to meals	Metabolized to GAZT Renal excretion of GAZT Dosage adjustment in renal insufficiency recommended (See Appendix B, Table 7.)	1.1 hrs/ 7 hrs	• Bone marrow suppression: macrocytic anemia or neutropenia • Nausea, vomiting, headache, insomnia, asthenia • Nail pigmentation • Lactic acidosis/severe hepatomegaly with hepatic steatosis (rare but potentially life-threatening toxicity) • Hyperlipidemia • Insulin resistance/diabetes mellitus • Lipoatrophy • Myopathy
Combivir ZDV with 3TC	Combivir ZDV 300 mg + 3TC 150 mg	Combivir 1 tablet BID			
Trizivir ZDV with 3TC+ABC	Trizivir ZDV 300 mg + 3TC 150 mg + ABC 300 mg	Trizivir 1 tablet BID			

Appendix B, Table 2. Characteristics of Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) (Updated October 14, 2011)

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7)	Elimination	Serum Half-life	Adverse Events (Also see Table 13)
Delavirdine (DLV)/ Rescriptor	100-, 200-mg tablets	400 mg TID (Four 100-mg tablets can be dispersed in at least 3 oz. of water to produce a slurry; 200-mg tablets should be taken as intact tablets.) Take without regard to meals.	CYP3A4 substrate and inhibitor; 51% excreted in urine (<5% unchanged) and 44% in feces	5.8 hrs	• Rash*. • Increased transaminase levels. • Nausea, headache.
Efavirenz (EFV)/ Sustiva **Also available as**:	• 50-, 200-mg capsules • 600-mg tablet	600 mg once daily at or before bedtime. Take on an empty stomach to reduce side effects.	Metabolized by CYPs 2B6 and 3A4 CYP3A4 mixed inducer/inhibitor (more an inducer than an inhibitor)	40–55 hrs	• Rash*. • Neuropsychiatric symptoms†. • Increased transaminase levels. • Hyperlipidemia. • False-positive results reported with some cannabinoid and benzodiazepine screening assays. • Teratogenic in nonhuman primates and potentially teratogenic in humans.
Atripla EFV with TDF + FTC	(EFV 600 mg + FTC 200 mg + TDF 300 mg) tablet	1 tablet once daily at or before bedtime.			
Etravirine (ETR)/ Intelence	• 100-, 200-mg tablets	200 mg BID. Take following a meal.	CYP3A4, 2C9, and 2C19 substrate 3A4 inducer; 2C9 and 2C19 inhibitor	41 hrs	• Rash, including Stevens-Johnson syndrome*. • Hypersensitivity reactions (HSRs) have been reported, characterized by rash, constitutional findings, and sometimes organ dysfunction, including hepatic failure. • Nausea.
Nevirapine (NVP)/ Viramune or Viramine XR	• 200-mg tablet • 400-mg XR tablet • 50-mg/5-mL oral suspension	200 mg once daily for 14 days (lead-in period); thereafter, 200 mg BID or 400 mg (Viramune XR tablet) once daily. Take without regard to meals. Repeat lead-in period if therapy is discontinued for more than 7 days. In patients who develop mild-to-moderate rash without constitutional symptoms, continue lead-in period until rash resolves but no longer than 28 days total.	CYP450 substrate, inducer of 3A4 and 2B6; 80% excreted in urine (glucuronidated metabolites, <5% unchanged); 10% in feces	25–30 hrs	• Rash, including Stevens-Johnson syndrome*. • Symptomatic hepatitis, including fatal hepatic necrosis, has been reported: - rash can be seen in approximately 50% of cases); - occurs at significantly higher frequency in ARV-naive female patients with pre-NVP CD4 counts >250 cells/mm^3 or in ARV-naive male patients with pre-NVP CD4 counts >400 cells/mm^3. NVP should not be initiated in these patients unless the benefit clearly outweighs the risk.
Rilpivirine (RPV)/ Edurant **Also available as:**	• 25-mg tablet	25 mg once daily. Take with a meal.	CYP3A4 substrate	50 hrs	• Rash*. • Depression, insomnia, headache
Complera RPV with TDF + FTC	RPV 25 mg + TDF 300 mg + FTC 200 mg	1 tablet once daily with a meal.			

Key to Abbreviations: BID = twice daily; CYP = cytochrome P; FTC = emtricitabine; TDF = tenofovir disoproxil fumarate; XR = extended release

* Rare cases of Stevens-Johnson syndrome have been reported with most NNRTIs; the highest incidence of rash was seen with NVP.

† Adverse events can include dizziness, somnolence, insomnia, abnormal dreams, confusion, abnormal thinking, impaired concentration, amnesia, agitation, depersonalization, hallucinations, and euphoria. Approximately 50% of patients receiving EFV may experience any of these symptoms. Symptoms usually subside spontaneously after 2–4 weeks, but may necessitate discontinuation of EFV in a small percentage of patients.

Appendix B, Table 3. Characteristics of Protease Inhibitors (PIs) (Updated January 10, 2011)

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7)	Elimination	Serum Half-life	Storage	Adverse Events (Also see Table 13)
Atazanavir (ATV)/ Reyataz	100-, 150-, 200-, 300-mg capsules	ARV-naïve patients: 400 mg once daily or (ATV 300 mg + RTV 100 mg) once daily With TDF or for ARV-experienced patients: (ATV 300 mg + RTV 100 mg) once daily With EFV in ARV-naïve patients: (ATV 400 mg + RTV 100 mg) once daily (For dosing recommendations with H_2 antagonists and proton pump inhibitor (PPIs), refer to Table 16a) Take with food	CYP3A4 inhibitor and substrate Dosage adjustment in hepatic insufficiency recommended (See Appendix B, Table 7.)	7 hrs	Room temperature (up to 25ºC or 77ºF)	• Indirect hyperbilirubinemia • PR interval prolongation: First degree symptomatic atrioventricular (AV) block reported. Use with caution in patients with underlying conduction defects or on concomitant medications that can cause PR prolongation. • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia • Nephrolithiasis • Skin rash (20%) • Serum transaminase elevations • Hyperlipidemia (especially with RTV boosting)
Darunavir (DRV)/ Prezista	75-, 150-, 300-, 400-, 600-mg tablets	ARV-naïve patients or ARV-experienced patients with no DRV mutations: (DRV 800 mg + RTV 100 mg) once daily ARV-experienced patients with at least one DRV mutation: (DRV 600 mg + RTV 100 mg) BID Unboosted DRV is **not** recommended Take with food	CYP3A4 inhibitor and substrate	15 hrs (when combined with RTV)	Room temperature (up to 25ºC or 77ºF)	• Skin rash (10%): DRV has a sulfonamide moiety; Stevens-Johnson syndrome and erythrema multiforme have been reported. • Hepatotoxicity • Diarrhea, nausea • Headache • Hyperlipidemia • Serum transaminase elevation • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia
Fosamprenavir (FPV)/ Lexiva (a prodrug of amprenavir [APV])	• 700-mg tablet • 50-mg/mL oral suspension	ARV-naïve patients: • FPV 1,400 mg BID or • (FPV 1,400 mg + RTV 100–200 mg) once daily or • (FPV 700 mg + RTV 100 mg) BID PI-experienced patients (once-daily dosing **not** recommended): • (FPV 700 mg + RTV 100 mg) BID With EFV: • (FPV 700 mg + RTV 100 mg) BID or • (FPV 1,400 mg + RTV 300 mg) once daily *Tablet*: Take without regard to meals (if not boosted with RTV tablet) *Suspension*: Take without food *FPV w/RTV tablet*: Take with meals	APV is a CYP3A4 substrate, inhibitor, and inducer Dosage adjustment in hepatic insufficiency recommended (See Appendix B, Table 7.)	7.7 hrs (APV)	Room temperature (up to 25ºC or 77ºF)	• Skin rash (12%–19%) – FPV has a sulfonamide moiety • Diarrhea, nausea, vomiting • Headache • Hyperlipidemia • Serum transaminase elevation • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia • Nephrolithiasis

Appendix B, Table 3. Characteristics of Protease Inhibitors (PIs)
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Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7)	Elimination	Serum Half-life	Storage	Adverse Events (Also see Table 13)
Indinavir (IDV)/ Crixivan	100-, 200-, 400-mg capsules	800 mg every 8 hrs Take 1 hour before or 2 hours after meals; may take with skim milk or low-fat meal With RTV: (IDV 800 mg + RTV 100–200 mg) BID Take without regard to meals	CYP3A4 inhibitor and substrate Dosage adjustment in hepatic insufficiency recommended (See Appendix B, Table 7.)	1.5–2 hrs	Room temperature (15º–30ºC/ 59º–86ºF) Protect from moisture	• Nephrolithiasis • GI intolerance, nausea • Hepatitis • Indirect hyperbilirubinemia • Hyperlipidemia • Headache, asthenia, blurred vision, dizziness, rash, metallic taste, thrombocytopenia, alopecia, and hemolytic anemia • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia
Lopinavir + Ritonavir (LPV/r)/ Kaletra	Tablets: (LPV 200 mg + RTV 50 mg) or (LPV 100 mg + RTV 25 mg) Oral solution: Each 5 mL contains (LPV 400 mg + RTV 100 mg) Oral solution contains 42% alcohol	LPV/r 400-mg/100-mg BID or LPV/r 800-mg/200-mg once daily Once-daily dosing is not recommended for patients with ≥3 LPV-associated mutations, pregnant women, or patients receiving EFV, NVP, FPV, NFV, carbamazepine, phenytoin, or phenobarbital. With EFV or NVP (PI-naïve or PI-experienced patients): LPV/r 500-mg/125-mg tablets BID (Use a combination of two LPV/r 200-mg/50-mg tablets + one LPV/r 100-mg/25-mg tablet to make a total dose of LPV/r 500 mg/125 mg.) or LPV/r 533-mg/133-mg oral solution BID *Tablet*: Take without regard to meals *Oral solution*: Take with food	CYP3A4 inhibitor and substrate	5–6 hrs	Oral tablet is stable at room temperature. Oral solution is stable at 2°–8°C (36°–46°F) until date on label and is stable when stored at room temperature (up to 25ºC or 77ºF) for 2 months.	• GI intolerance, nausea, vomiting, diarrhea • Pancreatitis • Asthenia • Hyperlipidemia (especially hypertriglyceridemia) • Serum transaminase elevation • Hyperglycemia • Insulin resistance/diabetes mellitus • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia • PR interval prolongation • QT interval prolongation and torsades de pointes have been reported; however, causality could not be established.
Nelfinavir (NFV)/ Viracept	• 250-, 625-mg tablets • 50-mg/g oral powder	1,250 mg BID or 750 mg TID May dissolve tablets in a small amount of water; once dissolved, patients should mix the cloudy liquid well and consume it immediately. Take with food	CYP2C19 and 3A4 substrate—metabolized to active M8 metabolite; CYP 3A4 inhibitor	3.5–5 hrs	Room temperature (15º–30ºC/ 59º–86ºF)	• Diarrhea • Hyperlipidemia • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia • Serum transaminase elevation

Appendix B, Table 3. Characteristics of Protease Inhibitors (PIs)

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7)	Elimination	Serum Half-life	Storage	Adverse Events (Also see Table 13)
Ritonavir (RTV)/ Norvir	• 100-mg soft gel capsules • 100-mg tablets • 80-mg/mL oral solution Oral solution contains 43% alcohol	As pharmacokinetic booster for other PIs: 100–400 mg per day in 1–2 divided doses (refer to other PIs for specific dosing recommendations) *Tablet*: Take with food *Capsule and oral solution*: Take with food, if possible, to improve tolerability.	CYP3A4 >2D6 substrate; potent 3A4, 2D6 inhibitor	3–5 hrs	Refrigerate capsules. Capsules can be left at room temperature (up to 25ºC or 77ºF) for up to 30 days. Tablets do not require refrigeration. Oral solution should **not** be refrigerated; store at room temperature 20º–25ºC (68º–77ºF).	• GI intolerance, nausea, vomiting, diarrhea • Paresthesias—circumoral and extremities • Hyperlipidemia (especially hypertriglyceridemia) • Hepatitis • Asthenia • Taste perversion • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia
Saquinavir tablets and hard gel capsules (SQV)/ Invirase	• 500-mg tablets • 200-mg hard gel capsules	(SQV 1,000 mg + RTV 100 mg) BID Unboosted SQV is **not** recommended. Take with meals or within 2 hours after a meal	CYP3A4 inhibitor and substrate	1–2 hrs	Room temperature (15º–30ºC/ 59º–86ºF)	• GI intolerance, nausea, and diarrhea • Headache • Serum transaminase elevation • Hyperlipidemia • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia • PR interval prolongation • QT interval prolongation, torsades de pointes have been reported. Patients with pre-SQV QT interval >450 msec should not receive SQV (See Table 5b.).
Tipranavir (TPV)/ Aptivus	• 250-mg capsules • 100-mg/mL oral solution	(TPV 500 mg + RTV 200 mg) BID Unboosted TPV is **not** recommended. *TPV taken with RTV **tablets**:* Take with meals *TPV taken with RTV **capsules** or **solution**:* Take without regard to meals	Cytochrome P450 3A4 inducer and substrate Net effect when combined with RTV (CYP 3A4, 2D6 inhibitor)	6 hrs after single dose of TPV/r	Refrigerate capsules. Capsules can be stored at room temperature (25ºC or 77ºF) for up to 60 days. Oral solution should **not** be refrigerated or frozen and should be used within 60 days after opening the bottle.	• Hepatotoxicity: Clinical hepatitis (including hepatic decompensation and hepatitis-associated fatalities) has been reported; monitor closely, especially in patients with underlying liver diseases. • Skin rash (3%–21%): TPV has a sulfonamide moiety; use with caution in patients with known sulfonamide allergy. • Rare cases of fatal and nonfatal intracranial hemorrhages have been reported. Risks include brain lesion, head trauma, recent neurosurgery, coagulopathy, hypertension, alcoholism,, use of anti-coagulant or anti-platelet agents including vitamin E. • Hyperlipidemia • Hyperglycemia • Fat maldistribution • Possible increased bleeding episodes in patients with hemophilia

Appendix B, Table 4. Characteristics of Integrase Inhibitor (Updated January 10, 2011)

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Serum half-life	Route of Metabolism	Adverse Events (Also see Table 13)
Raltegravir (RAL)/ Isentress	400 mg tablets	400 mg BID With rifampin: 800 mg BID Take without regard to meals	~9 hrs	UGT1A1-mediated glucuronidation	• Nausea • Headache • Diarrhea • Pyrexia • CPK elevation, muscle weakness and rhabdomyolysis

Appendix B, Table 5. Characteristics of Fusion Inhibitor (Updated January 29, 2008)

Generic Name (abbreviation)/ Trade Name	Formulations	Dosing Recommendation	Serum half-life	Elimination	Storage	Adverse Events (Also see Table 13)
Enfuvirtide (T20)/ Fuzeon	• Injectable—supplied as lyophilized powder • Each vial contains 108 mg of T20; reconstitute with 1.1mL of sterile water for injection for delivery of approximately 90mg/1mL.	90 mg (1mL) subcutaneously BID	3.8 hrs	Expected to undergo catabolism to its constituent amino acids, with subsequent recycling of the amino acids in the body pool	Store at room temperature (up to 25ºC or 77ºF). Reconstituted solution should be refrigerated at 2ºC–8ºC (36ºF–46Fº) and used within 24 hours.	• Local injection site reactions in almost 100% of patients (pain, erythema, induration, nodules and cysts, pruritus, ecchymosis) • Increased bacterial pneumonia • Hypersensitivity reaction (<1%): Symptoms may include rash, fever, nausea, vomiting, chills, rigors, hypotension, or elevated serum transaminases. Rechallenge is not recommended.

Appendix B, Table 6. Characteristics of CCR5 Antagonist (Updated January 29, 2008)

Generic Name (abbreviation)/ Trade Name	Formulation	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Serum Half-life	Elimination	Adverse Events (Also see Table 13)
Maraviroc (MVC)/ Selzentry	150-, 300-mg tablets	• **150 mg BID** when given with strong CYP3A inhibitors (with or without CYP3A inducers) including PIs (except TPV/r) • **300 mg BID** when given with NRTIs, T-20, TPV/r, NVP, RAL, and other drugs that are not strong CYP3A inhibitors or inducers • **600 mg BID** when given with CYP3A inducers, including EFV, ETR, etc. (without a CYP3A inhibitor) Take without regard to meals	14–18 hrs	CYP3A4 substrate	• Abdominal pain • Cough • Dizziness • Musculoskeletal symptoms • Pyrexia • Rash • Upper respiratory tract infections • Hepatotoxicity • Orthostatic hypotension

Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Updated October 14, 2011)

See reference section following tables for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

Antiretrovirals Generic Name (abbreviation)/Trade Name	Usual Daily Dose (Refer to Appendix B Tables 1–6 for additional dosing information)	Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis [CAPD] and hemodialysis [HD])	Dosing in Hepatic Impairment
Nucleoside Reverse Transcriptase Inhibitors **Use of fixed-dose combination NRTI (+/- NNRTI) of Atripla, Combivir, Trizivir, or Epzicom is not recommended in patients with CrCl <50 mL/min. Use of Truvada is not recommended in patients with CrCl <30 mL/min.**			
Abacavir (ABC)/ Ziagen	300 mg po BID.	No dosage adjustment necessary.	**Child-Pugh Score** — **Dose** 5–6 — 200 mg BID (use oral solution) >6 — Contraindicated
Didanosine enteric coated (ddI)/ Videx EC	**Body weight ≥60 kg**: 400 mg po once daily. **Body weight <60 kg**: 250 mg po once daily.	**Dose (once daily)** **CrCl (mL/min)** — **≥60 kg** — **<60 kg** 30–59 — 200 mg — 125 mg 10–29 — 125 mg — 125 mg <10, HD, CAPD — 125 mg — use oral solution	No dosage adjustment necessary.
Didanosine oral solution (ddI)/ Videx	**Body weight ≥60 kg**: 200 mg po BID or 400 mg po once daily. **Body weight <60 kg**: 250 mg po once daily or 125 mg po BID.	**Dose (once daily)** **CrCl (mL/min)** — **≥60 kg** — **<60 kg** 30–59 — 200 mg — 150 mg 10–29 — 150 mg — 100 mg <10, HD, CAPD — 100 mg — 75 mg	No dosage adjustment necessary.
Emtricitabine (FTC)/ Emtriva	200 mg oral capsule po once daily; or 240 mg (24 mL) oral solution po once daily.	**Dose** **CrCl (mL/min)** — **Capsule** — **Solution** 30–49 — 200 mg q48h — 120 mg q24h 15–29 — 200 mg q72h — 80 mg q24h <15 or HD — 200 mg q96h — 60 mg q24h Take dose after HD session on dialysis days.	No dosage recommendation.
Lamivudine (3TC)/ Epivir	300 mg po once daily; or 150 mg po BID.	**CrCl (mL/min)** — **Dose** 30–49 — 150 mg q24h 15–29 — 1 x 150 mg, then 100 mg q24h 5–14 — 1 x 150 mg, then 50 mg q24h <5 or HD — 1 x 50 mg, then 25 mg q24h Take dose after HD session on dialysis days.	No dosage adjustment necessary.
Stavudine (d4T)/ Zerit	**Body weight ≥60 kg**: 40 mg po BID. **Body weight <60 kg**: 30 mg po BID.	**Dose** **CrCl (mL/min)** — **≥60 kg** — **<60 kg** 26–50 — 20 mg q12h — 15 mg q12h 10–25 or HD — 20 mg q24h — 15 mg q24h Take dose after HD session on dialysis days.	No dosage recommendation.
Tenofovir (TDF)/ Viread	300 mg po once daily.	**CrCl (mL/min)** — **Dose** 30–49 — 300 mg q48h 10–29 — 300 mg twice weekly <10 not on HD — no recommendation HD — 300 mg q7d Take dose after HD session on dialysis days.	No dosage adjustment necessary.
Emtricitabine (FTC) + **Tenofovir** (TDF)/ Truvada	1 tablet po once daily.	**CrCl (mL/min)** — **Dose** 30–49 — 1 tablet q48h <30 or HD — not recommended	No dosage recommendation.
Zidovudine (AZT, ZDV)/ Retrovir	300 mg po BID.	**CrCl (mL/min)** — **Dose** <15 or HD — 100 mg TID or 300 mg once daily	No dosage recommendation.
Non-Nucleoside Reverse Transcriptase Inhibitors			
Delavirdine (DLV)/ Rescriptor	400 mg po TID.	No dosage adjustment necessary.	No dosage recommendation; use with caution in patients with hepatic impairment.

Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency

Antiretrovirals Generic Name (abbreviation)/ Trade Name	Daily Dose	Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis [CAPD] and hemodialysis [HD])	Dosing in Hepatic Impairment
Non-Nucleoside Reverse Transcriptase Inhibitors			
Efavirenz (EFV)/ Sustiva	600 mg po at or before bedtime.	No dosage adjustment necessary.	No dosage recommendation; use with caution in patients with hepatic impairment.
Efavirenz (EFV) + **Tenofovir** (TDF) + **Emtricitabine** (FTC) Atripla	1 tablet po once daily.	Not recommended if CrCl <50 mL/min; use individual drug components of fixed-dose combination and adjust TDF and FTC doses per CrCl.	
Etravirine (ETR)/ Intelence	200 mg po BID.	No dosage adjustment necessary.	Child-Pugh Class A or B: no dosage adjustment. Child-Pugh Class C: no dosage recommendation.
Nevirapine (NVP)/ Viramune or Viramune XR	200 mg po BID or 400 mg po once daily (using Viramune XR formulation).	HD patients: limited data; no dosage recommendation.	Child-Pugh Class A: no dosage adjustment. Child-Pugh Class B or C: contraindicated.
Rilpivirine (RVP)/ Edurant	25 mg po once daily.	No dosage adjustment necessary.	Child-Pugh Class A or B: no dosage adjustment. Child-Pugh Class C: no dosage recommendation.
Rilpivirine (RPV) + **Tenofovir** (TDF) + **Emtricitabine** (FTC)/ Complera	1 tablet po once daily.	Not recommended if CrCl <50 mL/min; use individual drug components of fixed-dose combination and adjust TDF and FTC doses per CrCl.	Child-Pugh Class A or B: no dosage adjustment. Child-Pugh Class C: no dosage recommendation.
Protease Inhibitors			
Atazanavir (ATV)/ Reyataz	400 mg po once daily or (ATV 300 mg + RTV 100 mg) po once daily.	No dosage adjustment for patients with renal dysfunction not requiring HD. ARV-naive patients on HD: (ATV 300 mg + RTV 100 mg) once daily. ARV-experienced patients on HD: ATV or RTV-boosted ATV not recommended.	**Child-Pugh Score** **Dose** 7–9 300 mg once daily >9 not recommended RTV boosting is **not** recommended in patients with hepatic impairment (Child-Pugh Score ≥7).
Darunavir (DRV)/ Prezista	(DRV 800 mg + RTV 100 mg) po once daily (ARV-naive patients) or (DRV 600 mg + RTV 100 mg) po BID.	No dosage adjustment necessary.	Mild-to-moderate hepatic impairment: no dosage adjustment. Severe hepatic impairment: not recommended.
Fosamprenavir (FPV)/ Lexiva	1,400 mg po BID or (FPV 1,400 mg + RTV 100–200 mg) po once daily or (FPV 700 mg + RTV 100 mg) po BID.	No dosage adjustment necessary.	**Child-Pugh Score** **Dose** PI-naive patients only: 5–9 700 mg BID 10–15 350 mg BID PI-naive or PI-experienced patients: 5–6 700 mg BID + RTV 100 mg once daily 7–9 450 mg BID + RTV 100 mg once daily 10–15 300 mg BID + RTV 100 mg once daily
Indinavir (IDV)/ Crixivan	800 mg po q8h.	No dosage adjustment necessary.	Mild-to-moderate hepatic insufficiency because of cirrhosis: 600 mg q8h.
Lopinavir/ritonavir (LPV/r) Kaletra	400/100 mg po BID or 800/200 mg po once daily.	Avoid once-daily dosing in patients on HD.	No dosage recommendation; use with caution in patients with hepatic impairment.
Nelfinavir (NFV)/ Viracept	1,250 mg po BID.	No dosage adjustment necessary.	Mild hepatic impairment: no dosage adjustment. Moderate-to-severe hepatic impairment: do not use.
Ritonavir (RTV)/ Norvir	As a PI-boosting agent: 100–400 mg per day.	No dosage adjustment necessary.	Refer to recommendations for the primary PI.
Saquinavir (SQV)/ Invirase	(SQV 1,000 mg + RTV 100 mg) po BID.	No dosage adjustment necessary.	Mild-to-moderate hepatic impairment: use with caution. Severe hepatic impairment: contraindicated.
Tipranavir (TPV)/ Aptivus	(TPV 500 mg + RTV 200 mg) po BID.	No dosage adjustment necessary.	Child-Pugh Class A: use with caution. Child-Pugh Class B or C: contraindicated.

Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency

Antiretrovirals Generic Name (abbreviation)/ Trade Name	Daily Dose	Dosing in Renal Insufficiency	Dosing in Hepatic Impairment
Fusion Inhibitor			
Enfuvirtide (T20)/ Fuzeon	90 mg subcutaneous BID.	No dosage adjustment necessary.	No dosage adjustment necessary.
CCR5 Antagonist			
Maraviroc (MVC)/ Selzentry	The recommended dose differs based on concomitant medications and potential for drug-drug interactions. See **Appendix B, Table 6** for detailed dosing information.	**CrCl <30 mL/min or HD** Without potent CYP3A inhibitors or inducers: 300 mg BID; reduce to 150 mg BID if postural hypotension occurs. With potent CYP3A inducers or inhibitors: not recommended.	No dosage recommendations. Concentrations will likely be increased in patients with hepatic impairment.
Integrase Inhibitor			
Raltegravir (RAL)/ Isentress	400 mg BID.	No dosage adjustment necessary.	Mild-to-moderate hepatic insufficiency: no dosage adjustment necessary. Severe hepatic insufficiency: no recommendation.

Key to Abbreviations: ARV = antiretroviral; BID = twice daily; CAPD = chronic ambulatory peritoneal dialysis; CrCl = creatinine clearance; CYP = chtochrome P; EC = enterec coated; HD = hemodialysis; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; PI = protease inhibitor; po = orally; TID = three times daily; XR = extended release

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Creatinine Clearance Calculation	
Male: $\frac{(140 - \text{age in years}) \times \text{weight (kg)}}{72 \times \text{Serum Creatinine}}$	Female: $\frac{(140 - \text{age in years}) \times \text{weight (kg)} \times 0.85}{72 \times \text{Serum Creatinine}}$

Child-Pugh Score			
Component	**Points Scored**		
	1	**2**	**3**
Encephalopathy*	None	Grade 1–2	Grade 3–4
Ascites	None	Mild or controlled by diuretics	Moderate or refractory despite diuretics
Albumin	>3.5 g/dL	2.8–3.5 g/dL	<2.8 g/dL
Total bilirubin or	<2 mg/dL (<34 μmol/L)	2–3 mg/dL (34 μmol/L to 50 μmol/L)	>3 mg/dL (>50 μmol/L)
Modified total bilirubin†	<4 mg/dL	4–7 mg/dL	>7 mg/dL
Prothrombin time (seconds prolonged) or	<4	4–6	>6
International normalized ratio (INR)	<1.7	1.7–2.3	>2.3

* Encephalopathy Grades
Grade 1: Mild confusion, anxiety, restlessness, fine tremor, slowed coordination
Grade 2: Drowsiness, disorientation, asterixis
Grade 3: Somnolent but rousable, marked confusion, incomprehensible speech, incontinence, hyperventilation
Grade 4: Coma, decerebrate posturing, flaccidity
† Modified total bilirubin used to score patients who have Gilbert's syndrome or who are taking indinavir or atazanavir

Child-Pugh Classification	Total Score*
Class A	5–6 points
Class B	7–9 points
Class C	>9 points

* Sum of points for each component